GE Healthcare

Lullaby™
LED Phototherapy System
Operation and Maintenance Manual

Operation and Maintenance Manual
English
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Rev F
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Scope

This manual provides a comprehensive description of the components of Lullaby LED Phototherapy System and its operation and maintenance details.

Indications for Use

The Lullaby LED Phototherapy System is used for the treatment of indirect hyper-bilirubinemia in term and pre-term infants, in a hospital environment – NICUs, PICUs and Well-baby Nurseries - administered by trained, professional medical staff, on the order of a licensed medical practitioner.

The Lullaby LED PT system is intended for use under the direct supervision of a licensed healthcare practitioner.

The Lullaby LED PT system device is not intended to be operated in mobile vehicles including ambulances or other vehicles associated with health care facilities.

Intended Users

This device should only be operated by health care providers who are trained in its operation and familiar with the risks of this type of device.

Purpose

The manual provides a complete guide on how to install, use and maintain the Lullaby LED Phototherapy System. Detailed technical information has been enumerated for the benefit of the user to facilitate correct and effective application of the device.

Symbol Definition

The following table describes the symbols and its inferences.

Symbol	Description
	This symbol denotes “Caution, read accompanying documents.” This applies also to when the Caution symbol appears on an equipment label. It means additional information is found in the accompanying documents.
WARNING	A WARNING statement is used when the possibility of injury exists.
	A General Warning statement is used to inform the users of the equipment on possible risk or injury.

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Symbol	Description
NOTE	A NOTE provides additional information to clarify a point in the text.
	Cover the patient's eyes while administering phototherapy.
	Over Temperature Cut-off Indicator
	Power OFF
	Power ON
	Low Irradiance
	High Irradiance
	Maintain 35 cm minimum distance between light source and infant
	European Union Representative
	Manufacturer—The symbol shall be accompanied by the name and the address of the manufacturer.
	WEEE Symbol
	CE Mark
	DC Current
REF	Part number of Lullaby LED Phototherapy System
SN	Serial Number of Lullaby LED Phototherapy System
	Lamp life timer

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Symbol	Description
	Refer to instruction manual/booklet
	Do not move the incubator with the device on it.
	Do not cover the vent
℞ ONLY US	Prescription Device Label for United States.

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It is important to know and understand the safety measure to be followed before using the phototherapy device. The precautions mentioned below are to prevent possible risk of injury to the patient or the operator and ensure correct usage of the equipment.

WARNINGS

- **Possible Risks**: All phototherapy methods have possible risks including, but not limited to, bronze baby syndrome, diarrhea, hyper-pigmentation, minor erythema, skin reddening, skin blistering, and potential retinal damage. Monitor the patient closely for signs of these conditions during phototherapy.
- **Photo Isomers**: Bilirubin photo isomers might cause toxic effects.
- **Porphyrins**: Porphyrins are the by-products of the photochemical break down of the bilirubin molecule. In some cases, exposure of porphyrins to phototherapy could result in a localized reddening of the patient's skin. Therefore, skin assessment is recommended with all types of phototherapy per hospital policy.
- **Photosensitive Drugs**: The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.
- **Dehydration and Insensible Water Loss**: The radiant energy from phototherapy lights can increase a patient's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while administering phototherapy.
- **Skin Temperature**: Phototherapy light may affect the temperature in thermoregulation devices (incubator, radiant warmers or heated mattresses) and could result in raising the patient's body temperature when the device is in use. It is recommended to use an incubator, warmer or bassinet in skin controlled (servo) mode. Always monitor the patient's temperature to avoid temperature fluctuations during phototherapy as per hospital policy.
- **Reflective Foils**: Using reflective foils to increase the efficacy of phototherapy may cause hazardous increase in patient's body temperature.
- **Eye Protection**: Do not look directly into the lamps. During treatment, always protect the patient's eyes with protective eyewear. Periodically, as per hospital protocol, verify that the patient's eyes are protected and free of irritation.
- **Operator Safety**: Users may experience headache, nausea or mild vertigo if the user remains in the irradiated area for a prolonged period of time. Using the Lullaby LED Phototherapy System in a well-lit area or wearing glasses with yellow lenses can alleviate potential effects.
- **Regular monitoring**: During treatment it is recommended to follow the measures as specified in the following guidelines:
  - Measure the patient's bilirubin level periodically during treatment per hospital guidelines.
  - Turn off the light when checking the patient's condition and skin color.
  - Follow standard procedures for monitoring patient temperature and fluid status.
  - Verify that the patient's eyes are protected and free of irritation as per hospital guidelines.
  - Maintain a distance of 35 cm between the light unit and the patient for optimal light intensity.

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- **Adjusting Height:** Do not adjust the height of the equipment with the patient directly under the unit. Secure the light unit in position before placing the patient under the device for therapy.
- Do not place the device in the path of any elevating bed.
- **Hot surface**: The lens surface on the lamp enclosure assembly could be as hot as 70 °C during operation. Do not touch the lens when the lamps are in ON condition.

The LED Phototherapy system , as with any electrical equipment must be must be handled with care to avoid damage to the equipment. Follow the below mentioned precautions with regard to the device.

⚠ **CAUTION**

- Following EMC Regulation: Medical Electrical Equipment needs to be installed and put into service strictly according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Environment: When using the Lullaby LED Phototherapy System adjacent to other equipment, it is important to verify normal operation in the configuration in which it is used.
- Do not use the Lullaby LED Phototherapy System in the presence of flammable anesthetics or gases to prevent any possibility of explosion under these conditions.
- When using the Lullaby LED Phototherapy System with Warmer ensure that the Lamp enclosure is not in the heat path of the Warmer.

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The Lullaby LED Phototherapy System is intended to treat infants suffering from neonatal hyperbilirubinemia, commonly known as neonatal jaundice. This section describes, in brief, the various parts of the Lullaby LED Phototherapy System.

NOTE: Before using this device read the safety information.

2.1 Features

The Lullaby LED Phototherapy System consists of the Lamp enclosure, Pedestal Assembly and Base assembly.

Part Illustration

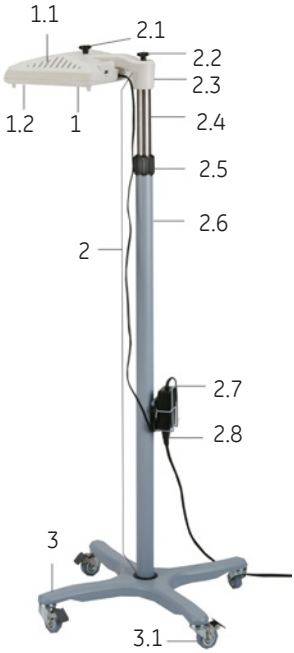

Figure 2-1 : LED phototherapy System

Function

1. **Lamp Enclosure**: The Lamp enclosure has 10 LED lamps enclosed in a plastic housing, which forms the light source. It consists of two parts- the upper enclosure and the lower enclosure. The lamp enclosure can be tilted to approximately 90° from the horizontal position.
   1.1 **Air-vent**: The air vents provide ventilation to the device when it is in use.
   1.2 **Handle**: Depression provided on either side to help hold the Lamp enclosure.
2. **Pedestal Assembly**: The pedestal consists of the following parts:
   - **Knobs:** The knobs secure the Lamp enclosure to the Arm (2.3). By removing the knobs the Lamp enclosure can be detached and used independently.

   2.1 **Tilt knob**: This knob can be loosened to tilt the lamp enclosure.
   2.2 **Securing Knob**: The retaining knob secures the lamp enclosure to the Arm (2.3).
   2.3 **Arm**: The Arm is fixed to the pedestal and supports the lamp enclosure.
   2.4 **Inner tube**: This part supports the Arm (2.3). The inner tube can be adjusted to vary the height of the lamp enclosure.
   2.5 **Height Adjust Lock**: This part secures the inner tube at the desired height.
   2.6 **Outer tube**: This part is fixed to the Base.
   2.7 **SMPS Holder**: This part is attached to the outer tube to place the SMPS (DC power supply).
   2.8 **SMPS with power cord**: The power unit with power cables to supply power to the unit.

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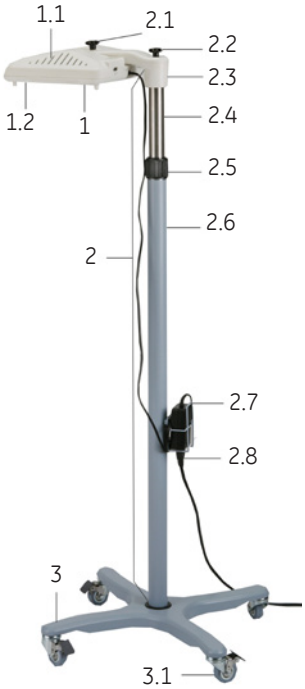
Part Illustration



Function

3. **Base Assembly**: The base is designed to provide stability at any height or angle of the lamp enclosure.
   3.1 **Casters with brake**: The swivel casters add mobility to the device. The brakes on each caster, when actuated, prevents movement.

Note: To move the equipment hold the unit below the height adjust lock.

2.3 Controls, Indicators, Mechanical controls

This section describes, in detail, the components of the Lullaby LED Phototherapy System.

2.3.1 Controls

Figure 2-2 : DC Jack

DC Jack (Refer Figure 2-2): The device is powered by a 24V SMPS. The power supply cable from the SMPS is connected to the DC jack on the lamp enclosure.

⚠ **WARNING**

1. The use of power cords and SMPS other than those specified by the manufacturer might affect the performance of the unit and could result in damage to the unit.
2. It may also create an unsafe operating condition, exposing a user to electric shock.

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Figure 2-3 : Lamp enclosure

Power ON/OFF Switch (Refer 1 of Figure 2-3): This switch turns ON and OFF the power supply to the device.

WARNING

Disconnect the power cord to completely cut-off the power supply to the device.

Irradiance Selection Switch (Refer 2 of Figure 2-3): The irradiance selection switch is used to select light intensity-low or high irradiance.

Air Vent (Refer 3 of Figure 2-3): The air vents helps to circulate the air inside the lamp enclosure and maintain its temperature when in use.

WARNING

Ensure that the air vents are not covered or obstructed when the unit is being used.

2.3.2 Indicators

Figure 2-4 : Over temperature cut-off indicator

Over Temperature Cut-Off Indicator (Refer Figure 2-4): This indicator glows when the device shuts down due to over temperature (exceeds 85°C) inside the lamp enclosure.

NOTE: In normal operating condition this indicator is OFF.

Figure 2-5 : Lamp life timer

Lamp Life Timer (Refer Figure 2-5): The Lamp life timer indicates the number of hours the LED lamps have been used.

NOTE: GEHC recommends, replacing the lamp after 50000 hours.

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2.3.3 Mechanical Controls

Figure 2-6 : Height adjust lock

Height Adjust Lock (Refer Figure 2.6): This part secures the inner tube at the desired height. The inner tube is released when the lock is turned counterclockwise allowing the height of the lamp enclosure to be adjusted.

WARNING

Always support the lamp enclosure with one hand when releasing the lock to adjust the height.

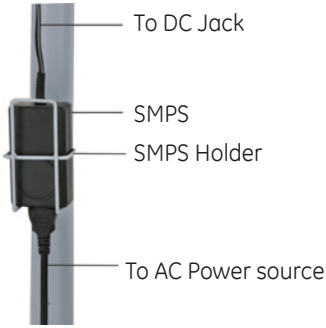

Figure 2-7 : SMPS with power cables in SMPS holder

SMPS Holder (Refer Figure 2-7): The holder is fixed to the outer tube to support the SMPS (power supply unit).

SMPS (Refer to Figure 2-7): The power supply unit is connected with power cables. The cable is connected to the DC jack, on the Lamp enclosure, at one end and to the AC power source on the other.

CAUTION

Wrap the excess cord around the SMPS holder to avoid the cord from trailing when moving or using the device.

Figure 2-8 : Base Assembly

Base (Refer Figure 2-8): The base keeps the device unit in a stable position.

Casters with position lock (Refer Figure 2-9): The swivel centre casters offer easy mobility in all directions. The casters can be kept in place by locking it in position using the brake lever.

WARNING

1. Always support the pedestal with one hand while locking or unlocking the casters.
2. Ensure that the brakes on all four casters are unlocked before moving the unit.

Figure 2-9 Caster with brake lever

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The following section describes the operating procedure of the device. For detailed instructions on installing and setup refer to Chapter 3 : Installing and Setup, in Service manual (2054622-001).

3.1 Operating Instructions

The following section provides step-by-step instructions to ensure that the Lullaby LED Phototherapy System provides effective phototherapy treatment:

- Read this manual and all accompanying documents.
- Note the WARNING and CAUTION statements that appear in this manual and all accompanying documents.
- Read the User Responsibility Statement available in the beginning of this manual.
- Read the Warranty: It describes GE Healthcares' responsibility in case of a functional defect.
- Keep this manual and all accompanying documents for future reference.

3.2 Checking equipment before use

Before using the equipment inspect for the following:

- Examine the power cord and the light unit for obvious signs of damage. If damaged, do not put the unit in use and contact GE authorized, service personnel.
- Verify that air circulation vents on the light unit are not covered or obstructed.
- Check for the power supply, connect the power supply cord to the DC Jack on the light unit and the other end to the main power supply. Wrap the power cord around the SMPS holder to prevent tripping.
- Test the lamps, turn On the lamp On/Off switch on the rear end of the Lamp enclosure. Turn on the irradiance selection switch and observe the lamp illumination. Use the Ohmeda Medical Biliblanket Meter II to check the irradiance level.
- Ensure the light unit is securely locked to the pipe and the pedestal assembly. The light unit can be tilted to a maximum of 90° angle from the horizontal axis of the pedestal. Test the tilting mechanism.
- Ensure that the brakes on the wheel are actuated.

If any of the above activity does not perform as described , do not use the unit. Contact qualified service personnel.

3.3 Preparing an Infant for phototherapy

After completing the checkout procedures on the equipment it is important to follow the below mentioned procedures to get the maximum benefit of the treatment:

1. Remove the infant clothing. Leaving the diaper on is at the discretion of the attending physician.
2. Maximize skin surface area to be exposed to phototherapy treatment.
3. Cover the eyes of the infant using an appropriate eye shield.
4. If the baby has a skin temperature probe in place, ensure this is appropriately applied to the infants skin and cover with a reflective probe cover.

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5. Position the phototherapy unit over the infant and turn it ON. It is recommended to measure the irradiance level after positioning the device.

NOTE : Factors to consider when using any phototherapy device to ensure proper treatment include:

- Maximum body surface area exposed to phototherapy light
- Distance between the infant from the light source
- Intensity of light
- Duration of exposure to phototherapy
- Total serum bilirubin
- Skin thickness and pigmentation

3.4 Basic Operating Procedure

Below mentioned are the basic operating procedure of the Lullaby LED Phototherapy System.

3.4.1 Adjusting the height of the Lamp enclosure

WARNING

Adjust the height and distance of the Lamp enclosure before positioning the Lullaby LED Phototherapy System in therapy area.

NOTE: Do not adjust the height of the equipment with the patient directly under the unit.

3.4.1.1 Height Adjust Lock

Figure 3-1 : Height Adjust Lock

The height of the Inner tube can be altered with the Height adjust lock.

1. Hold the Inner tube with one hand.
2. Unscrew the Height adjust lock by turning it anti-clockwise. Adjust the inner-tube of the pedestal to increase or decrease the height.
3. Tighten the Height adjust lock by turning it clockwise at the desired height.

WARNING

1. Ensure that the Height adjust lock is secured tightly.
2. Ensure that the distance of the Lamp enclosure is not less than 35 cm from the patient.

3.4.2 Moving the device

The swivel casters allows to move the unit with ease in any direction, position the device in the intended location and actuate the brakes.

NOTE: Before moving the device ensure that the brakes on all four casters are unlocked.

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3.4.2.1 Swivel casters with brake

Figure 3-2 : Base with casters

Figure 3-3 : Casters with brakes actuated

1. Support the light unit with one hand.
2. Apply slight foot pressure on the locking lever to actuate or unlock the casters.

3.4.3 Powering-ON the system

Connecting the power cord

Figure 3-4 : SMPS Holder

1. Place the SMPS in the SMPS holder (Figure 3-4).
2. Connect the DC plug of the SMPS cable into the DC jack (Figure 3-5).
3. Fix the power cord to the SMPS (Figure 3-4) and connect the other end of the power cord to the mains supply.

⚠ **CAUTION**

Ensure that the power cord is not in the way of frequent movement to avoid accidental tripping.

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Figure 3-5 : DC Jack

Figure 3-6 : Power ON/OFF switch

Figure 3-7 : LED Phototherapy System with lamps ON

4. Turn ON the mains and the Power ON/OFF switch on the Lamp enclosure (Refer Figure 3-6). The blue LED lamps will glow (Figure 3-7).

3.4.4 Selecting Irradiance level

The intensity of the blue LED lamps can be controlled using the Irradiance selection switch.

3.4.4.1 Irradiance level

Figure 3-8 : Irradiance selection switch

1. Select the irradiance level. The symbol **II** on the switch indicates high intensity and **I** for low intensity. The nominal output at high intensity is: 45 µW/ cm^2/nm ±25% and 22 µW/ cm^2/nm ±25% at low intensity setting.

NOTE: Monitor the patient during treatment as per hospital guidelines.

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3.5 Tilting the Lamp enclosure

The Lamp enclosure can be tilted at an angle up to 90^0.

3.5.4.1 Tilting the light unit:

Figure 3-9 : Tilt knob

1. To tilt the Lamp enclosure loosen the Tilt knob, indicated in the figure, by turning it counter clockwise.
2. Tilt the unit to the desired angle as shown in Figure 3-9.
3. Tighten the Tilt knob by turning it clockwise.

WARNING

Always support the light unit with one hand when loosening or tightening the tilting knob.

Figure 3-10 : Tilted at an angle

3.6 Using with other devices

The device can be used independently or with other devices such as radiant warmer or incubator. When using it in such situations ensure that the heat source of the devices do not conflict or interfere with the functioning of other equipment.

CAUTION

Follow hospital guidelines and medical protocol when using LED Phototherapy System with other device.

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Figure 3-11 : Correct positioning of the LED phototherapy System when used with an Infant Warmer

Figure 3-12 : Incorrect positioning of the LED phototherapy System when used with an Infant Warmer

Figure 3-13 : Using the LED Phototherapy with an Incubator

NOTE: The Over heat indicator in the LED Phototherapy System may be activated if the device is not correctly aligned to the heat path of the Warmer.

The **Figure 3-12** shows the LED Phototherapy System in the path of the Warmer, which is incorrect.

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3.7 Using Lamp enclosure in detached condition

The Lamp enclosure can be detached from the pedestal and used as a standalone unit. This provides the flexibility to adapt the device to suit any environment.

Figure 3-14 : Removing the knobs

Figure 3-15 : Removing the upper arm

Figure 3-16 : Detaching the Lamp enclosure

Figure 3-17 : Using on an Incubator

1. Unplug the power cord from the DC jack.
2. Unscrew both the knobs (Tilt and Securing knob) on the Lamp enclosure (Figure 3-14).
3. Remove the upper arm (Figure 3-15)
4. Hold Lamp enclosure, tilt and lift it off from the Arm (Figure 3-16).
5. The Lamp enclosure can now be used safely over an incubator as shown in Figure 3-17. Attach the DC power supply cord in the DC jack and insert the plug to the main power supply, all other functionality of the Lamp enclosure remain the same.

Note: Ensure the SMPS (power supply) is properly supported and is not hanging free when used in detach mode.

⚠ WARNING

1. Do not to move the incubator when using the light unit as mentioned above.
2. Ensure that the air vents are not covered or obstructed when the unit is being used.
3. When used on top of an incubator there is a possibility of reduction in the peak irradiance at the incubator bed level. The irradiance will depend on the type of material and design of the incubator canopy.
4. The lens surface on the Lamp enclosure assembly could be as hot as 70 °C during operation. Do not touch the lens when the lamps are in ON condition.
5. Do not detach the unit whilst it is in ON condition.
6. Do not detach the unit whilst it is placed over an infant bed device.

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The following flowcharts describe likely symptoms, their causes and actions to be taken.

A- Damaged parts

B- Jammed Parts

C- Functionality Issues

A: Damaged Parts

A- When the following parts are damaged: Upper enclosure, Lower enclosure, Pedestal Assembly, Base Assembly. Refer to Figure 2-1 to identify the parts.

→ Remove the unit from service and contact GE-authorized and trained service personnel.

B: Jammed Parts

B1- Lamp enclosure is drooping

→ Y → Check for any visible damage to the lower arm. If there is any damage, remove the device from service and contact GE-authorized and trained service personnel.

N →

The Lower arm may not be properly engaged to the Inner tube. Remove the Upper arm cover and check the screws. If they are found to be loose, remove the device from service and contact GE-authorized service personnel.

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B2- Pedestal is sliding down

Y

Check if the Height lock is properly engaged on the threads of the Outer tube. Try to disengage and tighten again. If the problem persists follow the instructions, explained in the box below.

Y

Check if the Height lock inner is installed within the Outer lock. If there is no Height lock inner, remove the device from service and contact GE-authorized and trained service personnel.

B3- No Mobility

Y

Check if the brakes are actuated. If so, release them on all four wheels and try moving the device. If the problem persists, check for the following issue.

Y

Check the caster for visible damage, check for jammed brake levers. The part may need replacement. Remove the device from service and contact GE-authorized, trained service personnel.

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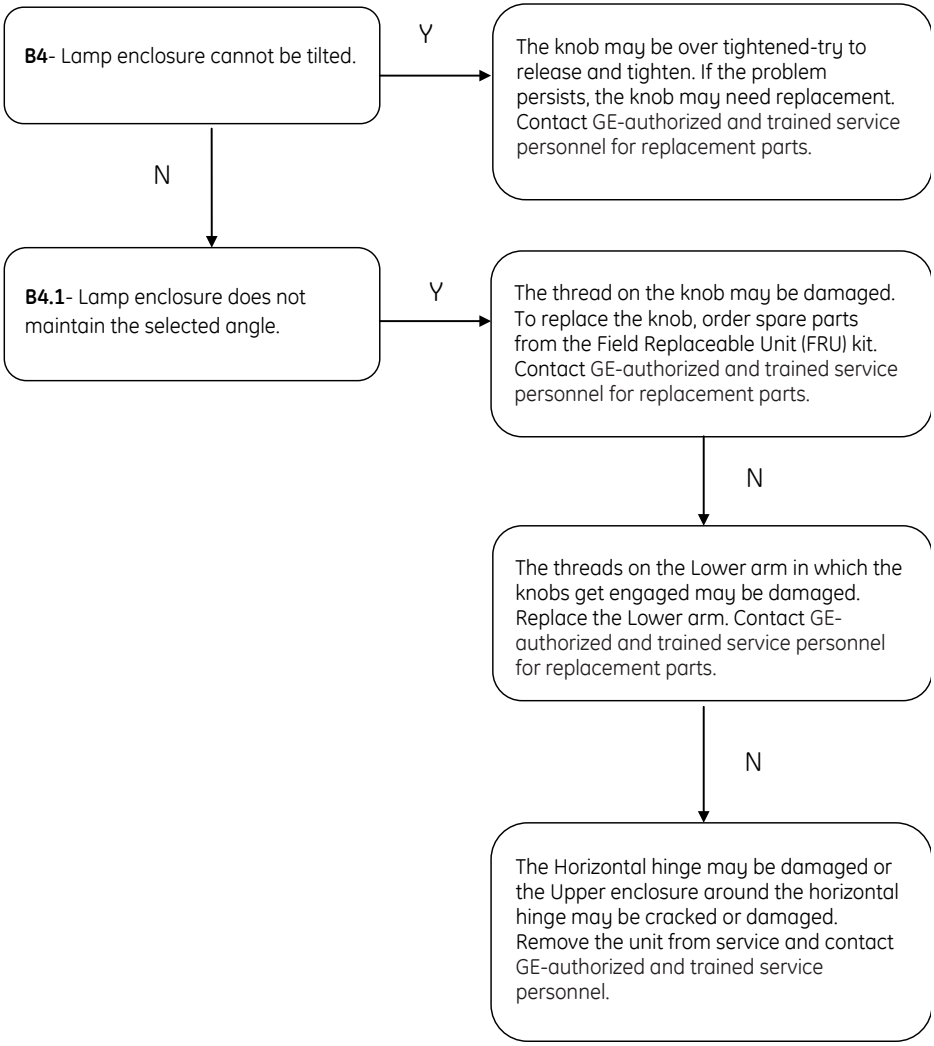
B4- Lamp enclosure cannot be tilted.
Y
The knob may be over tightened-try to release and tighten. If the problem persists, the knob may need replacement. Contact GE-authorized and trained service personnel for replacement parts.
N
B4.1- Lamp enclosure does not maintain the selected angle.
Y
The thread on the knob may be damaged. To replace the knob, order spare parts from the Field Replaceable Unit (FRU) kit. Contact GE-authorized and trained service personnel for replacement parts.
N
The threads on the Lower arm in which the knobs get engaged may be damaged. Replace the Lower arm. Contact GE-authorized and trained service personnel for replacement parts.
N
The Horizontal hinge may be damaged or the Upper enclosure around the horizontal hinge may be cracked or damaged. Remove the unit from service and contact GE-authorized and trained service personnel.

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C: Functionality Issues

C1- Lamp Hour Timer is not working

Y

The power supply to the unit is not ON. Switch the power ON. If the problem persists, remove the unit from service and contact GE-authorized, trained service personnel.

C2- Lamp unit overheated indicator is ON

Y

Turn OFF the mains switch and disconnect the power cords from the outlet

Ensure that the air vents on the light unit are not obstructed.

Ensure the area around the equipment is not congested and is well ventilated by air conditioning or natural means.

Allow the unit to cool down. The Overheated Indicator will reset when the unit cools. Start using the device after it resets.

Plug the power cord into an outlet. Turn the mains and the Power switch ON.

If still problem persist remove the unit from service and contact GE-authorized and trained service personnel.

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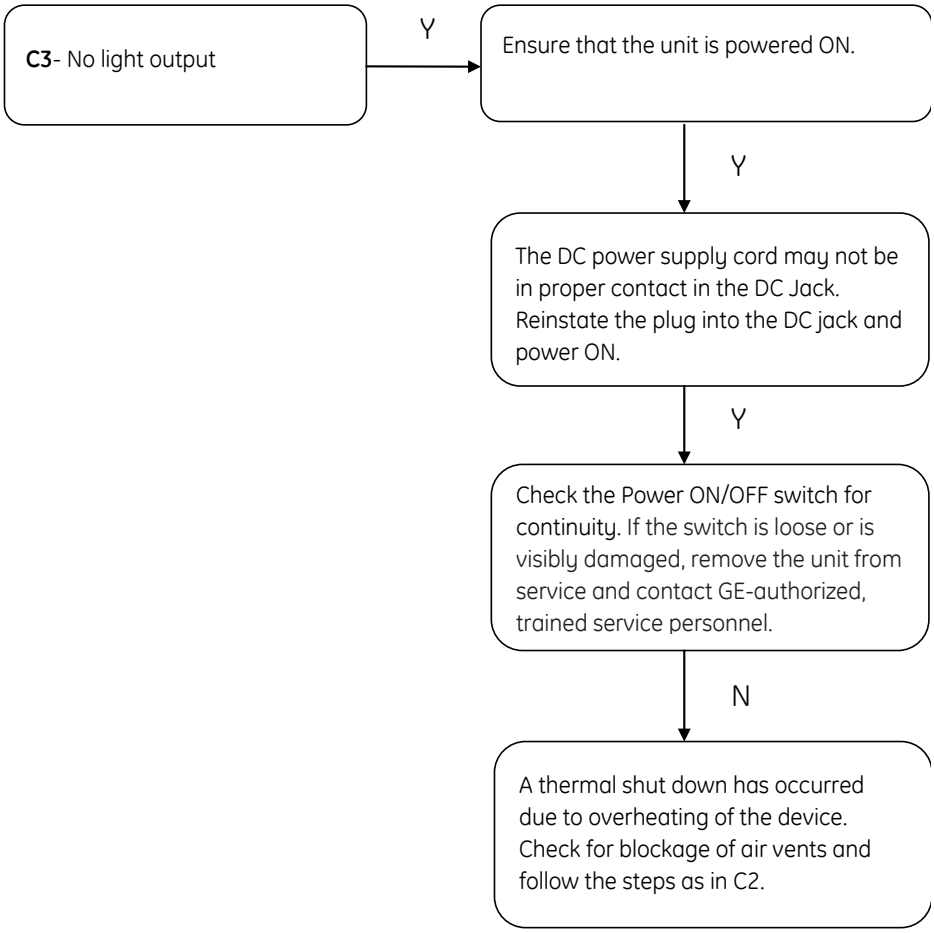
C3- No light output
Y
Ensure that the unit is powered ON.
Y
The DC power supply cord may not be in proper contact in the DC Jack. Reinstate the plug into the DC jack and power ON.
Y
Check the Power ON/OFF switch for continuity. If the switch is loose or is visibly damaged, remove the unit from service and contact GE-authorized, trained service personnel.
N
A thermal shut down has occurred due to overheating of the device. Check for blockage of air vents and follow the steps as in C2.

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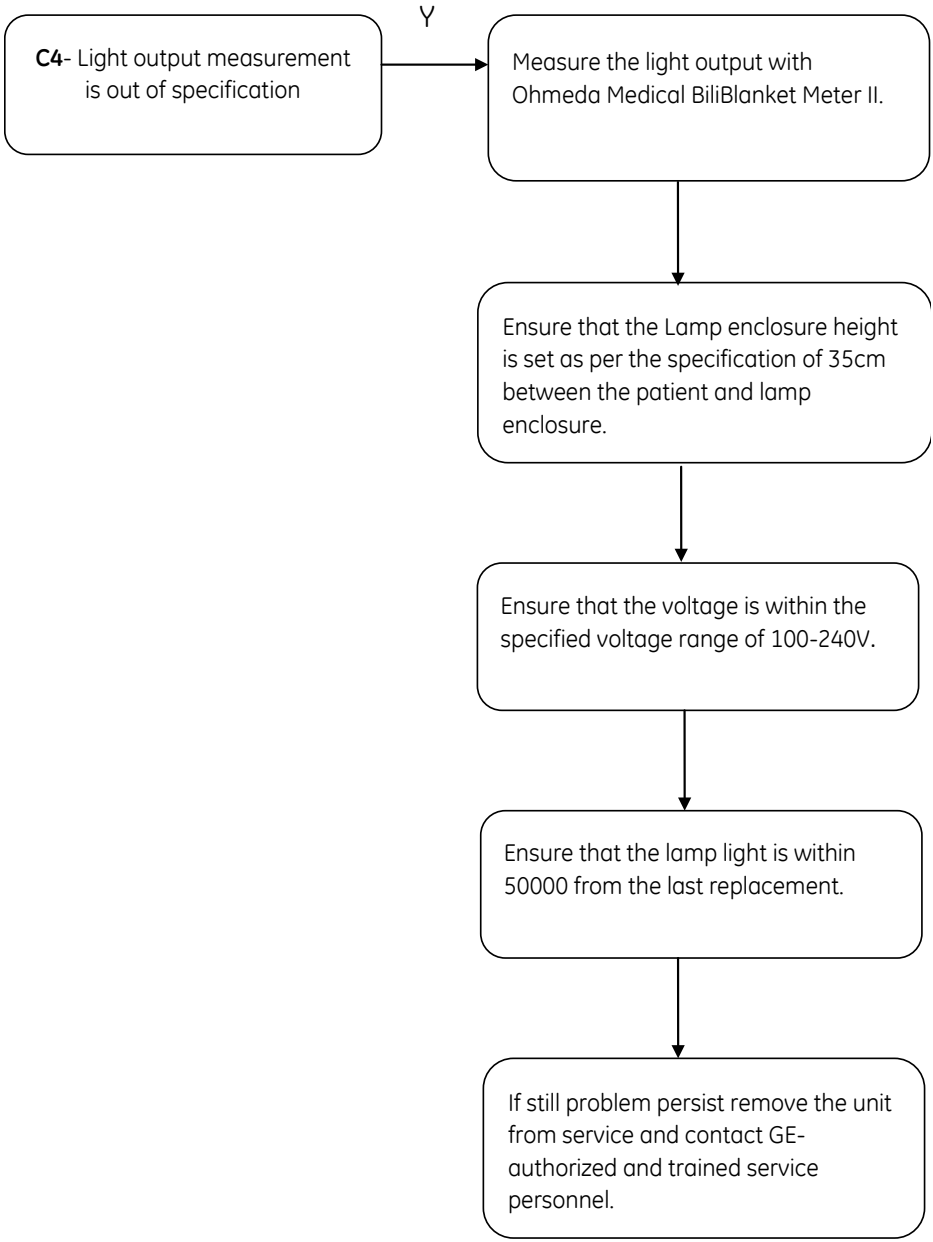
C4- Light output measurement is out of specification
Y
Measure the light output with Ohmeda Medical BiliBlanket Meter II.
Ensure that the Lamp enclosure height is set as per the specification of 35cm between the patient and lamp enclosure.
Ensure that the voltage is within the specified voltage range of 100-240V.
Ensure that the lamp light is within 50000 from the last replacement.
If still problem persist remove the unit from service and contact GE-authorized and trained service personnel.

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5.1 Cleaning

1. Ensure the mains power cord is disconnected from the power source before cleaning.
2. Use approved cleaning solution. Clean the outside of the light unit using a mild detergent solution. Aqueous solutions (hospital disinfectants and micro bactericides) may be used.
3. Apply the cleaning solutions with a clean cloth or sponge. Do not allow liquids to seep into the housing (air vents). Always dry the parts with a clean, damp, soft cloth to avoid scratches and remove any cleaner residue.
4. Do not spray cleaner directly on the unit.
5. Make sure that the unit is completely dry before using it.

The following table lists approved cleaning solution:

Generic Formulation	Maximum Concentration Level
Hydrogen Peroxide	6%
Sodium Hypochlorite	0.5% Aqueous Solution
Cavicide®	100% spray (Applied to cleaning cloth, not directly on equipment)
Glutaraldehyde	2%
Iodophor Solution	0.27%

5.2 Maintaining

It is necessary to maintain the equipment for optimum performance every time you use it

WARNING

Do not use a phenol compound-based cleaner. Phenol compounds have been associated with elevated bilirubin levels in infants.

CAUTION

1. Never immerse the light unit in liquid. It may cause electrical short-circuit resulting in permanent damage.
2. Use the cleaning solution sparingly on a cloth when cleaning the exterior of the light unit. Do not saturate the cloth; excessive solution could flow into the light unit and damage internal components.
3. Do not autoclave or gas sterilize the light unit.
4. Cleaning solutions such as iodine solutions will reduce the unit's light output. Do not use iodine solutions, strong acids, strong alkali, or bleach solutions to clean the unit.

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Appendix A: Specifications

NOTE: The specifications are subject to change without notice

Specifications	
20 W maximum at 100-240 V ~, 50/60 Hz	
Over temperature protection	Power cutoff for temperature greater than or equal to 85°C
Touch current	Less than 500 µA at 264 VAC RMS (power on) with ground intact for normal and reverse polarity and with ground open for normal and reverse polarity.
Environmental Operating Requirements	
Ambient temperature	+10°C to +40°C
Humidity	20% to 95% RH non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Storage and Transportation Requirements	
Temperature	0°C to +70°C
Humidity	10% to 95% RH non-condensing
Atmospheric pressure	50 kPa to 106 kPa
Performance Specifications	
Spectral Irradiance *Using an Ohmeda Medical BiliBlanket Meter II	High Irradiance Mode: 45 µW/ cm2/nm ±25%, 15-point check at a distance of 35 cm from the light unit
	Low Irradiance Mode: 22 µW/ cm2/nm ±25%, 15-point check at a distance of 35 cm from the light unit
Wavelength range	400 - 550 nm (Dominant wavelength range is 450 - 465 nm)
LED Lamps	Typical lamp life is approximately 50000 hours before an irradiance drop of 30%
Physical Specification	
Overall dimension (Lx Bx H)	530 mmx 550 mmx 1700 mm (at maximum height)
Regulatory Standards	
IEC Class 1 (continuous operation)	TÜV Rheinland CB certified to the following standards: IEC 60601-2-50; IEC 60601-1; IEC 60601-1-2
EMC Class -A, CISPR 11, Group 1	Certified under IECEE CB scheme

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B.1 Effective Surface Area

The effective surface area of irradiance at a distance of 35 cm from the bed surface is 50 cm x 30 cm, and the maximum irradiance is 45 µW/cm²/nm ±25% at the high irradiance mode. Once the phototherapy light is on and positioned over the patient, measure the spectral irradiance with Ohmeda Medical BiliBlanket Meter II.

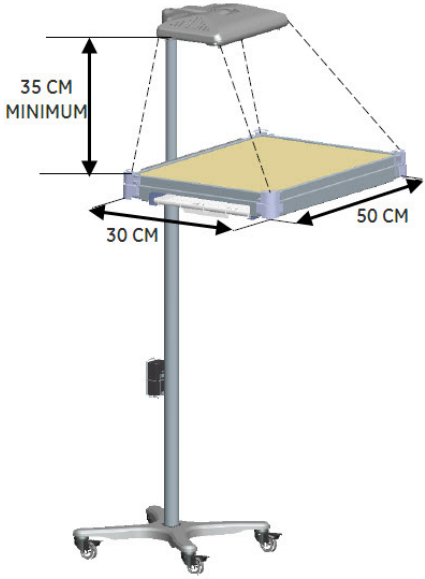

Figure B-1 : Effective Surface Area

B.1.1 Spectral Irradiance vs Distance

Distance from hood bottom to bed surface (cm)	Surface Area (L x W) (cm)	Irradiance Ebi max (µW/ cm²/nm)	Mean Irradiance (Ebi 15) (µW/ cm²/nm)
35	50 x 30	45	35
40	50 x 30	40	31
50	50 x 30	31	25

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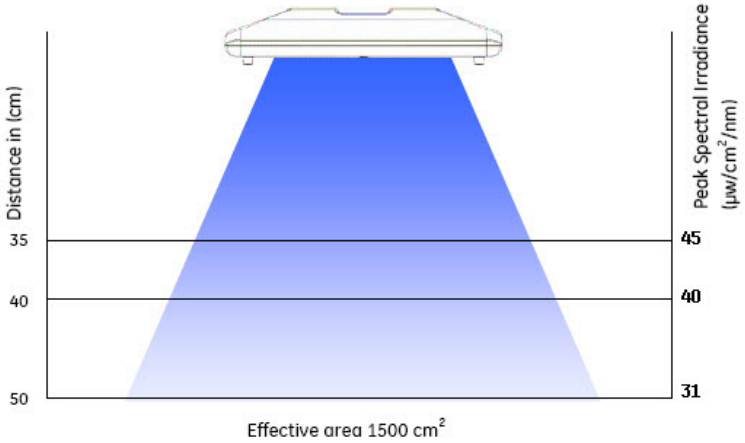

Figure B-2 : Spectral Irradiance Vs Distance

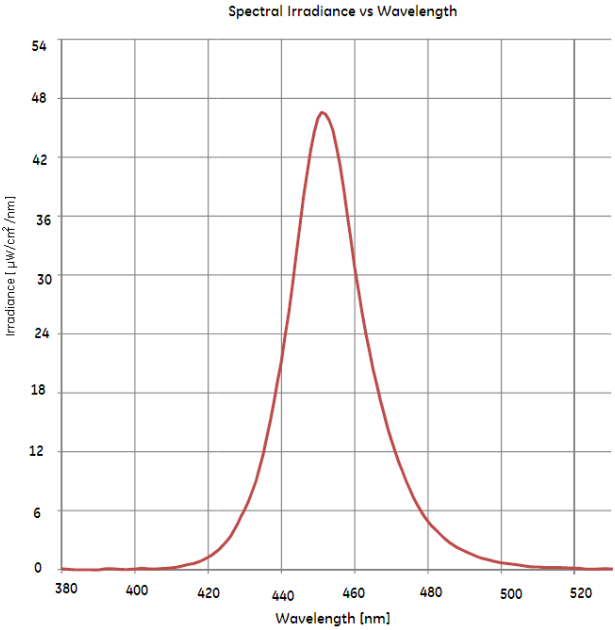

Figure B-3 : Spectral Response Curve

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B.2 Service Maintenance

The unit should be serviced and maintained by qualified service personnel. Follow hospital and local regulations for scheduled maintenance frequency.

B.3 Part Replacement

There are specific parts that can be replaced when it is damaged or is not performing as described. Contact a GE authorized personnel to know more about replaceable parts and when a replacement is required.

Note: Always use only GE Healthcare replacement parts. Failure to use authentic parts may result in malfunctioning of the equipment.

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Appendix C: Electromagnetic Compatibility (EMC)

Changes or modifications to this system not expressly approved by GEHealthcare could cause EMC failures with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows:

⚠ **CAUTION**

1. Use of portable phones or other radio frequency (RF)-emitting equipment near the system could cause unexpected or adverse operation.
2. The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

C.1 Electromagnetic Emission

The Lullaby LED Phototherapy System is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Lullaby LED Phototherapy System is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment -Guidance
RF emissions EN 55011	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The equipment is suitable for hospital or clinic use only. The equipment should not be used on public, low-voltage power networks that supply domestic buildings
RF emissions EN 55011	Class A	
Harmonic Emissions EN 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions EN 61000-3-3	Complies	

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD)EN 61000-4-2	± 6kV contact ± 8kV air	± 6 kV contact ±8 kV air	Floors should be wood, concrete or air ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 20 %.

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Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical fast transient/burst EN 61000-4-4	±2kV for power supply lines ± 1kV for input/ output lines	±2kV for power supply lines ± 1kV for input/ output lines	Mains power quality should be that of a typical hospital environment.
Surge EN 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power should be that of a typical hospital environment. If the equipment requires continued operation during power mains interruptions, it is recommended that the Lullaby LED Phototherapy be powered from an uninterrupted power supply.
NOTE: U_T is the a.c mains voltage prior to application of test level.			
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3A / m	3A / m	Power frequency magnetic fields should be at levels of a typical hospital environment.
Conducted RF EN 61000-4-6	3 V rms, 150kHz to 80MHz	3 V rms	Interference could occur in the vicinity of equipment marked with the following symbol:
Radiated RF EN 61000-4-3 EN 60601-2-50	3V / m, 80MHz to 2.5GHz 10V / m,	3V / m, 10 V / m	

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Recommended separation distances between portable and mobile RF communications equipment and the Lullaby LED PT					
The Lullaby LED PT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lullaby LED PT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lullaby LED PT as recommended below, according to the maximum output power of the communications equipment.					
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (Meters)**				
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$		**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E1}\right]\sqrt{P}$	
	3Vrms	3V/m	10V/m	3V/m	10V/m
0.01	0.12	0.12	0.04	0.23	0.07
0.1	0.38	0.38	0.11	0.73	0.22
1	1.2	1.2	0.35	2.3	0.7
10	3.8	3.8	1.11	7.3	2.2
100	12	12	1.11	23	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in Meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C.2 CE Marking Information

Compliance

The Lullaby LED Phototherapy System bears the CE mark, indicating its conformity with the provisions of the Council Directive 93/42/EEC, concerning medical devices and fulfills the essential requirements of Annex I of this directive. Any other directive(s) and all the standards the product complies to are listed in the general information of the operator's manual. The country of manufacture can be found on the equipment labeling. The safety and effectiveness of this device has been verified against previously distributed devices. Although all the standards applicable to presently marketed devices may not be appropriate for prior devices (i.e. electromagnetic compatibility standards), this device will not impair the safe and effective use of those previously distributed devices.

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C.3 Recommendation

Users should be aware of known RF sources, such as radio or TV stations and hand-held or mobile two-way radios, and consider them when installing a medical device or system. Be aware that adding accessories or components, or modifying the medical device or system may degrade the EMI performance. Consult with qualified personnel regarding changes to the system configuration.

Operating the system near radio frequency (RF) electromagnetic interference (EMI) above the conditions defined in the EMC Standard EN60601-1-2 for Radiated Immunity (field strengths above 3 V/m) may cause malfunctions.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Review the AAMI Committee Technical Information Report (TIR) 18, “Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers”. This guidance document provides a means to evaluate and manage the EMI environment in the hospital. The following actions can be taken to reduce the risk of medical device EMI and achieve EMC:

- Assess the EMC environment of the healthcare facility (e.g., identify radio transmitters in around the facility) and identify areas where critical medical devices are used (e.g., ER, ICU, CCU, NICU).
- Increase the distance between sources of EMI and susceptible devices.
- Remove the devices that are highly susceptible to EMI.
- Lower the power transmitted from electrical and electronic equipment (EMI sources) under hospital control (i.e. paging systems).Label devices susceptible to EMI.
- Educate healthcare facility staff (nurses and doctors) to be aware of, and to recognize, potential EMI related problems.

Notes

LED Phototherapy System	
Description	**Number**
Serial number of the unit	

NOTE: For the serial number of the device, refer to the rating label on the Lamp assembly. Record the serial number of the device in the space provided above for reference.

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Warranty

This Product is sold by GE Healthcare under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from GE Healthcare or GE Healthcare's Authorized Dealers as new merchandise and are extended to the Buyer thereof, other than for the purpose of resale. For a period of twelve (12) months for the light unit from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by GE Healthcare to a GE Healthcare Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in this operation manual and accompanying labels and/or inserts, provided that the same is properly operated under the conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided.

The foregoing warranties shall not apply if the Product has been repaired other than by GE Healthcare or in accordance with written instructions provided by GE Healthcare, or altered by anyone other than GE Healthcare, or if the Product has been subject to abuse, misuse, negligence, or accident. GE Healthcare's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at GE Healthcare's option, a Product, which is telephonically reported to the nearest GE Healthcare Regional Service Office and which, if so advised by GE Healthcare, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated GE Healthcare Service Center during normal business hours, transportation charges prepaid, and which, upon GE Healthcare's examination, is found not to conform with above warranties. GE Healthcare shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages. There are no express or implied warranties, which extend beyond the warranties hereinabove, set forth. GE Healthcare makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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